

MULTI-FUNCTIONAL SECOND INSTRUMENT
FOR CATARACT REMOVAL

The present application is a continuation-in-part
5 of U.S. patent application S.N. _____ filed
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The present invention generally relates to surgical
instruments, and more particularly, relates to
10 apparatus which provides for improved irrigation and
reduced risk of corneal or sclera tissue damage during
cataract removal.

Cataracts cause the lens of an eye to become
15 clouded, and a common practice to alleviate this
condition is by surgically removing the cataractic
lens and replacing it with an artificial intraocular
lens.

20 Early lens removal was effected through manual
extraction which required a wound of about 12mm in
length. This large opening can result in corneal or
sclera tissue damage.

25 Phacoemulsification, on the other hand, enables
the removal of a cataractic lens through a much
smaller incision, for example, between about 2.5 to
about 4mm. In this procedure, a needle is inserted
30 through the incision into a lens capsule and the
needle is vibrated to mechanically emulsify the lens.
It is often desirable to utilize a second tool in
order to manipulate the lens toward and around the
phacoemulsification needle in order to more
effectively emulsify the lens. Once fragmented or
35 emulsified, the lens material is aspirated through a
lumen through the phacoemulsification needle.

Heretofore, while emulsifying the lens and aspirating lens fragments, a simultaneous flow of irrigation fluid into the lens capsule has been provided around the needle through an annulus established by a sleeve concentrically disposed over the needle. This flow of liquid into the eye is necessary to prevent collapse of the interior chamber of the eye during aspiration. In addition, the irrigation fluid cools the needle in order to prevent any thermal damage of the corneal or sclera tissue. While the sleeve surrounding a phacoemulsification needle provides the important function of establishing an annulus for introducing irrigation fluid into the lens capsule it also enlarges the overall diameter of the sleeve needle for which an incision must be made.

In addition, when irrigation fluid is introduced proximate the emulsifying needle tip, the immediate area in front of the needle is roiled. This occurs because of the counter-current flow of fluid being aspirated by the needle itself and the irrigation fluid being introduced over the surface of the needle. Needle vibration causes a cloud of debris which is roiled by the incoming infusion fluid which lessens the physician's visual acuity of the end of the needle which can slow the procedure. This roiling also pushes nuclear fragments away from the needle rendering the procedure less efficient.

The present invention overcomes the drawbacks of a sleeved phacoemulsification needle.

SUMMARY OF THE INVENTION

Apparatus in accordance with the present invention includes a first instrument for inserting into a lens capsule and removing a cataract therein,

the needle including a lumen therethrough for aspiration of lens tissue and irrigation fluid from said lens capsule through a primary aspiration port defined by an end of said lumen and a second 5 instrument for inserting into the lens capsule and manipulating the cataract as the cataract is being removed, said second instrument having an irrigation port for introducing the irrigation fluid into said lens capsule.

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More specifically, the second instrument may include a tip, such as a hook or blade, attached to a shaft for manipulating the cataract and the shaft includes a shaft lumen for delivery the irrigation 15 fluid to the irrigation port. Alternatively, the second instrument may include a conduit attached to the shaft, for delivering the irrigation fluid to the irrigation port. Further, a plurality of irrigation ports may be provided, each in fluid communication 20 with the shaft lumen or conduit.

More specifically, the first instrument may include a sonic or ultrasonic device needle for emulsifying the lens tissue. In this instance, the 25 needle includes a lumen for aspiration of emulsifying lens tissue and aspiration flow from the lens capsule.

BRIEF DESCRIPTION OF THE DRAWINGS

30 The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in which:

35 Figure 1 is a diagram of apparatus in accordance with the present invention generally showing a first needle for introducing an irrigation fluid into a lens

capsule through a handpiece from an operating console along with a second vibrated needle for inserting into the lens capsule and operated by a phacoemulsification handpiece connected to an aspiration line and 5 controlled by the console through an ultrasonic power line;

Figure 2 is a view of the vibrated needle shown in Figure 1 showing a primary aspiration port along 10 with two secondary aspiration ports formed in the needle in a spaced apart distance from the primary aspiration port;

Figure 3 is a view of the needle tip shown in 15 Figure 2 illustrating non-turbulent aspiration of lens tissue and irrigation fluid;

Figure 4 is a similar view of a prior art sleeved needle top illustrating turbulence or roiling of fluid 20 in front of the needle tip caused by countercurrent fluid flow with results in a cloud of emulsified lens tissue and repulsion of the same;

Figure 5 is a diagram of alternative apparatus in 25 accordance with the present invention generally showing a first instrument including a vibrated needle for inserting into a lens capsule and operation by a handpiece connected to an aspiration line and controlled by a console through a power line along 30 with a second instrument for inserting into the lens capsule for manipulating a cataract during removal thereof and for providing irrigation fluid to the lens capsule;

35 Figure 6 is an enlarged representation of a second instrument tip illustrating introduction of

irrigation fluid through irrigation ports from a lumen in a shaft supporting a tool tip;

5 Figure 7 is similar to Figure 6 illustrating the introduction of irrigation fluid through irrigation ports from a conduit adhered to a shaft supporting a tool tip; and

10 Figure 8 is similar to Figure 6 illustrating a different tool tip which may be fixed to a separate shaft or used as a replaceable tip.

DETAILED DESCRIPTION

15 With reference to Figure 1, there is shown apparatus 10 for the removal of lens tissue 12 which includes a first needle 14 for introducing an irrigation fluid indicated by the arrow 18 into a lens capsule 20.

20 Manipulation of the needle 14 within the lens capsule 20 is effected through a handpiece 24 which communicates to a control console 26 through an irrigation line 28. The control console 26 may be of 25 any suitable type as for example, one manufactured by Allergan, Inc., under the trade name Sovereign.

30 Also shown in Figure 1, as well as in Figure 2, is a second needle 32 which is ultrasonically vibrated by a handpiece 34. Any suitable handpiece may be utilized such as for example, one sold by Allergan, Inc., under the trade name Sovereign. The handpiece 34 is interconnected to the console 26 and control thereby through an aspiration line 38 and a power line

40 for controlling ultrasonic power delivered to the needle 32 by the handpiece 34.

The second needle 32 fragments or emulsifies the
5 cataractic lens 12 which is then aspirated along with irrigation fluid through a lumen 42 in the needle 32 as indicated by the arrow 44. Manipulation of the irrigating needle 14 is effective in enabling more efficient removal of the cataractic lens 12 as the
10 fluid is now a manipulation tool, moving fragments of lens 12 to the needle 32.

Because the needle 32 does not include a conventional sleeve (not shown in Figures 1 and 2) a
15 smaller incision or wound 50 is required. The wound size may be as small as 0.8mm which is to be compared with conventional sleeved needles (not shown) which would require a slit or wound opening, of about 2.5 to 3mm (or larger).

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As more clearly shown in Figure 2, the needle 32 includes a primary aspiration port 52 defined by the lumen 42 and one or more secondary aspiration ports 54, 56 disposed along a length 60 of the needle 32 between the primary aspiration port 52 and a hub 62 for attachment of the needle 32 to the handpiece 34.

The secondary aspiration ports 54, 56 may be spaced apart axially from the primary aspiration port
30 and one another as shown in Figure 2 or, alternatively, as shown in Figure 1, aspiration ports 64, 66 may be disposed along the needle 32 in a spaced apart radial relationship with one another resulting

in aspiration of fluid from the lens capsule 20 in opposing direction as indicated by the arrows 70, 72.

The secondary aspiration ports 54, 56, 64, 66 5 also provide an important function in maintaining the fluid flow through the needle should the primary aspiration port 52 become occluded. This insures cooling of the needle 32 to prevent overheating thereof. Preferably, the secondary aspiration ports 10 54, 56, 64, 66 are disposed within 6mm of the primary aspiration port to insure that their aspirating functionality is performed within the lens capsule 20. In order to insure that the majority of aspiration occurs through the primary aspiration port, it is 15 preferred that the total cross-sectional area of the secondary aspiration ports 54, 56, 64, 66 be no more than 10% of the cross-sectional area of the primary aspiration port 52.

20 The advantages of the unsleeved needle 32 are more clearly understood with reference to Figures 3 and 4. Figure 3 illustrates smooth laminar flow of aspiration fluid as shown by the arrows 78 into the primary aspiration port 52 and secondary aspiration 25 ports 64, 66.

This is to be contrasted with a conventional phacoemulsification needle tip 80 which is surrounded by a sleeve 82 for the introduction of irrigation 30 fluid proximate to an aspiration port 84 as indicated by the arrows 86. The sleeve 82 also has side holes 88 for irrigation outflow.

As illustrated, aspiration of fluid as indicated by the arrows 90, 92 may be partially diverted from the port 84 before entering which causes a roiling of the fluid indicated by the arrows 96, 98. This 5 roiling of fluid causes a "milky cloud" to appear proximate the needle tip 80 and pushes lens fragments away which interferes with the physician acuity of the needle tip 80 which interferes with efficient phacoemulsification of lens tissue, not shown in 10 Figure 4.

With reference to Figure 5, there is shown in an alternative embodiment 100 in accordance with the present invention, in reference, characters refer to a 15 similar or substantially identical elements hereinabove discussed in connection with the embodiment 10 shown in Figure 1.

Embodiment 100 includes a first instrument 102 20 which includes a vibrated needle 104 for inserting into a lens capsule 106 for removing a cataract 108 therein. The needle 104 includes a lumen 112 therethrough for aspiration of cataract tissue from the lens through a primary aspiration port 114 defined 25 by an end 116 of the needle 104, this aspiration is indicated by the arrow 118. Preferably, second aspiration ports 120, 122 are provided in the needle 112 for aspirating cataractic tissue, as well as irrigation fluid, from the lens capsule 106 as 30 indicated by the arrows 126, 128.

A second instrument 130, which includes a shaft 132 and tool tip 134, is inserted into the lens

capsule 106 for manipulating the cataract to 108 as the cataract 108 as being emulsified by the needle 104.

5 The second instrument 130 includes one or more irrigation ports 136, 138, 140 for introducing irrigation fluid into the eye capsule 106 as indicated by the arrows 140.

10 An enlarged view of the tool tip 34 and shaft 132 are shown in Figure 6. Irrigation fluid is provided to the ports 138, 140 shown in Figure 6 through a lumen 146 within the shaft 132. Alternatively, as shown in Figures 7, the tool tip 34 may be supported 15 by a solid shaft 148 and a separate conduit 150 may be utilized to provide irrigation fluid to irrigation ports 152, 154.

20 The tool tip 134 may be of any suitable type, such as for example, a hook or a blade, for manipulation of the cataractic tissue 108 and may be fixed to a shaft 148 as shown in Figure 7 or removably coupled to a shaft 132 by a conventional coupling mechanism 160. When a coupler 160 is utilized, 25 alternative tool tips 162, as shown in Figure 8, may be attached to the shaft 132 by the user.

30 The irrigation ports 138, 140, 152, 154 are preferably spaced apart axially on the shaft 132, 148 respectively or, as illustrated in Figure 5, there may be also space radially about the shaft. The size of the ports 138, 140, 152, 154 may be 0.6 to 1.5mm in order to introduce irrigation fluid at the rate of 20

- 60cc/min. The irrigation port 138, 140, 152, 154 size and location is dependant upon surgeon technique and incision location.

5 Although there has been hereinabove described apparatus for the removal of lens tissue in accordance with the present invention for the purposes of illustrating in which the manner in which the invention may be used to an advantage, it will be
10 appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations, or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as defined in the appended
15 claims.

RECORDED IN 35MM